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10/552,552	10/07/2005	Marc De Block	58764.000049	2007

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EXAMINER	
KUMAR, VINOD	

ART UNIT	PAPER NUMBER
1638	

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03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,552	DE BLOCK, MARC	
	Examiner	Art Unit	
	VINOD KUMAR	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of objections and rejections

1. Amendment filed in the paper of December 12, 2007 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8, and 17-21 are cancelled.

Claims 9-16 are pending.

Claims 9-16 are examined on merits in this Office action.

The objections to the specification have been withdrawn in light of amendments to the specification.

The objections to claims 9-13, and 16 have been withdrawn in light of claim amendments.

The rejection of claims 9-15 under 35 U.S.C. 101 for claiming the invention directed to non-statutory subject matter is withdrawn in light of claim amendments.

The rejection of claims 9-16 under 35 U.S.C. 112, 1st paragraph (written description) is withdrawn in light of the claim amendments.

The rejection of claims 9, and 11-15 under 35 U.S.C. 102(b) is withdrawn in light of the claim amendments.

This action is made FINAL.

Claim Objections

2. Claim 14 remains objected for the reason of record stated in the Office action mailed June 12, 2006. It is suggested to change "Seeds" to --A seed--.

Appropriate action is required.

Claim Rejections - 35 USC § 112

3. Claims 9-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection has been necessitated due to the claim amendment filed in the paper of December 12, 2007.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "further comprising an antisense nucleotide sequence of at least 20 consecutive nucleotides of the complement of a coding region of a nucleotide sequence encoding a protein comprising the amino acid sequence of SEQ ID No. 1 or of the complement of the nucleotide sequence of SEQ ID No. 3, wherein said sense and antisense nucleotide sequence are capable of forming a double stranded RNA region comprising said at least 20 consecutive nucleotides", which is confusing since it is unclear how an antisense sequence of the complementary sequence of a sense sequence would anneal with a sense sequence to form a double stranded RNA. An antisense sequence of a complementary sequence of a sense sequence would read on sense sequence. It is unclear what is intended. In order to form a double stranded inhibitory molecule, a sense and antisense sequences have to be complementary to

each other and separated by a spacer. Furthermore, it is unclear whether "a DNA" region as recited in part II of the claim is operably linked to the plant expressible promoter and transcription termination region.

Dependent claims 10-14 are also rejected because they fail to overcome the deficiencies of claim 9.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation “further comprising an antisense nucleotide sequence of at least 21 to 100 consecutive nucleotides of the complement of a nucleotide sequence encoding a protein comprising the amino acid sequence of SEQ ID No. 1 or the nucleotide sequence of SEQ ID No. 3, wherein said sense and antisense nucleotide sequence are capable of forming a double stranded RNA region comprising said at least 21 to 100 consecutive nucleotides”, which is confusing since it is unclear how the antisense sequence of the complementary sequence of a sense sequence would anneal with a sense sequence to form a double stranded RNA. An antisense sequence of a complementary sequence of a sense sequence would read on sense sequence. It is unclear what is intended. In order to form a double stranded inhibitory molecule, a sense and antisense sequences have to be complementary to each other and separated by a spacer. Furthermore, it is unclear whether "a DNA" region as recited in part II of the claim is operably linked to the plant expressible promoter and transcription termination region.

Dependent claim 15 is also rejected because it fails to overcome the deficiency of claim 16.

Appropriate action is required.

Claim Rejections - 35 USC § 112

4. Claims 9-16 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA molecule comprising a plant expressible promoter operably linked to an 163 bp of ParG coding sequence of SEQ ID NO: 3 (positions 973 to 1135) in sense and antisense orientation separated by an intron, and further operably linked to 3' transcription termination signals, to produce an inhibitory double-stranded RNA molecule when expressed in transgenic *Arabidopsis*, *Brassica* or tobacco plant, and wherein said transgenic plant exhibits high light stress tolerance, or a method of producing said transgenic plant using said DNA molecule, does not reasonably provide enablement for a DNA molecule comprising at least 20, or 21 to 100 nucleotides in sense and antisense orientation from any region of a nucleotide sequence encoding the protein of SEQ ID NO: 1. The claims contain subject matter which was not described in the specification in such a way as to enable any person skilled in the art to which it pertains, with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the reasons of record as stated in the Office action mailed on June 12, 2006. Applicant traverses the rejection in the paper filed on December 12, 2007.

Applicant argues that amendment to claims filed in the paper should overcome all enablement issues (response, pg 10, lines 1-5).

Applicant's argument was fully considered but was deemed to be unpersuasive.

It must be emphasized that the breadth of claims encompass inhibiting endogenous ParG gene expression in a plant (*Arabidopsis*, *Brassica* or tobacco) using 20, or 21 to 100 consecutive nucleotides of a nucleotide sequence encoding SEQ ID NO: 1. While the specification provides guidance on using 163 bp region (positions 973 to 1135) of SEQ ID NO: 3 in obtaining ParG gene suppression effect in transgenic *Arabidopsis* and tobacco plants, it does not provide guidance whether sequences of 20, or 21 to 100 bp in size and derived from any region of a nucleotide sequence encoding SEQ ID NO: 1 would produce ParG gene suppression effect when expressed in said plant species.

It is maintained that using DNA sequences to reduce expression of the endogenous corresponding gene through the mechanism of antisense/sense or dsRNAi based suppression methods is highly unpredictable. See for example, Arziman et al. (Nucleic Acids Research, 33:582-588, 2005) who teach that although a dsRNA should be designed to match to one specific gene, off-target effects can occur if SiRNAs have sequence homology to genes that are not supposed to be targeted. The knock-down of target might differ depending on the efficiency of SiRNA derived from long dsRNA. It is further maintained that the stability of a double-stranded RNA would also depend upon a number of factors, such as sequence composition (e.g., GC content), thermodynamic stability and sequence length etc.

In the absence of guidance, undue experimentation would have been required by a skilled artisan to determine how to use 20, or 21 to 100 consecutive bp of a nucleotide sequence encoding SEQ ID NO: 1, in a method of obtaining high light stress tolerance

transgenic plant through the gene suppression of endogenous ParG gene expression in said plant. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 102

5. Claims 9-16 remain rejected under 35 U.S.C. 102(a) as being anticipated by Chang et al. (WIPO, WO 03/000898, Published January 3, 2003, Applicant's IDS) for the reasons of record stated in the Office action mailed on June 12, 2007. Applicant traverses the rejection in the paper filed on December 12, 2007.

It is noted that Applicant's traversal did not include any arguments.

It is, therefore, maintained that Chang et al. disclose a transgenic plant and a method of making a transgenic plant comprising transformation of said plant with a DNA expression cassette comprising a plant-expressible promoter operably linked to a ParG (poly(ADP-ribose) glycohydrolase) nucleotide sequence as defined in SEQ ID NO: 550 which is identical in sequence to instant SEQ ID NO: 3, and wherein said nucleotide sequence is in antisense orientation relative to the promoter, and transcribes to yield a ParG molecule which inhibits the expression of endogenous ParG expression of the transformed plant. The reference also discloses down-regulation of endogenous ParG gene expression in a plant comprising transformation of a DNA construct comprising sense and antisense sequences of SEQ ID NO: 550 which yields a double stranded

RNAi (inhibitory molecule) to down-regulate or inhibit endogenous ParG gene expression in said plant. The reference discloses seeds of the transformed plant and a method of transferring said DNA expression cassette to a non-transgenic plant through crossing between said transgenic plant and the plant lacking said DNA expression cassette. The reference also discloses transgenic *Arabidopsis* or *Brassica* plants comprising said DNA expression cassette. See in particular, SEQ ID NO: 550; claims 27-57, 57-58, 63-67; pages 98-99, 100-108.

The property of tolerance to high light stress in the transgenic plant expressing ParG double stranded RNAi would also be inherent to the double stranded inhibitory RNA molecule comprising sense and antisense sequences of ParG coding sequence (SEQ ID NO: 550) disclosed in the reference.

Conclusions

6. Claims 9-16 remain rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is set to expire within TWO MONTHS of the mailing date of this final action and the advisory action is

not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)272-0975. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong T. Bui/

Primary Examiner, Art Unit 1638

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/552,552	DE BLOCK, MARC	
	Examiner	Art Unit	
	VINOD KUMAR	1638	